

ENZYMATIC THERAPY

1 N C C R P C R A T C CWhat **Better** feels like."

February 17, 2005

INTEGRATIVE THERAPEUTICS INC."

NF Formulas • PhytoPharmica
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 * F: 503.582.0467

ENZYMATIC THERAPY
&
PHYTOPHARMICA*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

Office of Nutritional Products, Labeling &

Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway

College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Hypo-Ade™	Supports healthy blood sugar levels that are already within normal range, between meals.*	Vitamin A (as beta carotene and as retinyl acetate), Vitamin C (as ascorbic acid), Thiamin (as thiamin HCI) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCI), Vitamin B12 (as cyanocobalamin), Pantothenic Acid (as calcium D-pantothenate), Zinc (as zinc gluconate), Manganese (as manganese gluconate), Chromium (as chromium picolinate), Potassium (as potassium aspartate), Inositol, Pancreas Extract, Choline Bitartrate, L-Methionine, Beet Root, Adrenal Extract, Betaine HCI, Wild Yam (Dioscorea villosa) Root, Barberry (Berberis vulgaris) Bark of Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву: _		fillest							
•	F	Rob	ert C	. Do	ster				
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Title: Senior Vice President of Scientific Affairs

Date: 2/11/05

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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

Chief Financial Officer



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*

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Hypo-Ade™	May reduce sugar cravings*	Vitamin A (as beta carotene and as retinyl acetate), Vitamin C (as ascorbic acid), Thiamin (as thiamin HCI) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCI), Vitamin B12 (as cyanocobalamin), Pantothenic Acid (as calcium D-pantothenate), Zinc (as zinc gluconate), Manganese (as manganese gluconate), Chromium (as chromium picolinate), Potassium (as potassium aspartate), Inositol, Pancreas Extract, Choline Bitartrate, L-Methionine, Beet Root, Adrenal Extract, Betaine HCI, Wild Yam (Dioscorea villosa) Root, Barberry (Berberis vulgaris) Bark of Root Extract

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Ву:	fillellt	

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/18/05

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Sincerely,

Michael P. Devereux Chief Financial Officer